

REMARKS

Claims 1-23 currently are pending in the application. Claims 1, 15 and 23 have been amended. No new matter has been added by these amendments. Applicants have carefully reviewed the positions presented in the Office Action and respectfully request reconsideration of the claims in view of the remarks presented below.

Claim Rejections Under 35 U.S.C. §103

Claims 1-23 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,395,366 to D'Andrea et al. (D'Andrea) in view of U.S. Patent No. 5,711,299 to Manwaring et al. (Manwaring). Applicants respectfully traverse.

When manipulating an interventional device through a body cavity, it is not unusual for a clinician to manipulate the device through points previously traversed. This duplicative nature necessarily increases the time it takes to locate a target within the cavity as well as the overall time for the procedure. The present invention solves this problem by providing a system and method for assisting the clinician in guiding a device to a target in a more efficient manner. Specifically, independent claims 1, 15 and 23 have been amended to recite a clinician-manuevered device providing an indication of when the device is maneuvered through points in an anatomical site previously traversed. By eliminating the guesswork as to whether a maneuver has been repeated, the device allows the clinician to efficiently move the device to the intended target.

D'Andrea discloses an ingestible capsule for gathering a fluid sample in the alimentary canal. First, a signal transmitting exploratory capsule is ingested and passed through the canal with its geographic route being mapped to the precise route that the capsule would take to a specific location in the canal. Using the mapped route, subsequent capsules with sampling means may be ingested to take fluid samples upon arrival of the capsule at a desired site (see column 3, lines 26-47). Unlike the present invention, a reading of D'Andrea discloses that it is concerned with finding the precise canal location for taking a fluid sample (see column 3, lines 12-29). It does not teach or suggest facilitating the most efficient way for the device to traverse the canal, as taught by the present invention. Furthermore, while the device in D'Andrea is similar to the present invention because it provides position data to a clinician, it is inherently

different from the present invention in that it moves independently within the canal without the guiding hand of the clinician. Thus, the information transmitted by the D'Andrea device is solely for the purpose of mapping the device route as it passes through the canal. It cannot serve as an indication to the clinician that the device has moved through a point in the canal previously traversed to prompt the clinician to alter the path of the device because the clinician has no control over how the D'Andrea device maneuvers. In view of this, D'Andrea cannot be shown to disclose, teach or suggest the present invention found in independent claims 1, 15 and 23 because it does not assist a clinician in maneuvering a clinician-maneuvered device to a target in a more efficient manner by providing an indication when the device is maneuvered through points in the anatomical site previously traversed.

Manwaring discloses a system for tracking the movement of a surgical instrument relative to a trajectory from an initial point to a target during a surgical procedure. Prior to surgery, a surgeon determines the path the instrument will take according to various factors such as the location of the target, the type of surgical procedure to be performed, critical or eloquent areas that must be avoided and the surgical position of a body. During surgery, the surgeon causes the surgical instrument to follow the pre-determined trajectory with the assistance of the system (see column 4, lines 10-22). A feedback device is used to indicate whether the surgical instrument is aligned or misaligned with the trajectory.

The present invention is completely unlike what is disclosed in Manwaring in that a pre-determined trajectory is unnecessary prior to surgery so as not to confine a surgeon to a fixed path. As enabled by independent claims 1, 15 and 23, wherein position coordinate data of a device is tracked, the surgeon is free to choose his own path to a target site, yet will still be able to reach the target in an efficient manner because the device indicates whether the surgeon is maneuvering in an area previously traversed. Furthermore, unlike Manwaring, the exact location of the device within the anatomical site is known because the position coordinate data of the device is tracked. In contrast, only the position of the device relative to a trajectory is tracked in Manwaring. Although the Examiner recognizes on page 3 of the Office action that Manwaring provides for coordinate data of a trajectory to be stored in a database, Applicants must respectfully contend that tracking the coordinates of a trajectory that a device is meant to follow is very dissimilar from tracking the coordinates of a device's exact location. Nowhere in

Manwaring is tracking the exact location of the device within the anatomical site taught or even suggested. In fact, a reading of Manwaring teaches away from this practice (see column 2, lines 7-9: "...systems that precisely locate and orient the instrument may overly restrict the amount of positional freedom available to the surgeon;" and column 10, lines 18-20: "System 10 tracks the alignment of surgical instrument 12 relative to trajectory 26 rather than locating the exact position of surgical instrument 12 at all times.").

In view of the foregoing, Applicants submit that neither D'Andrea nor Manwaring, either alone or in combination, teach or suggest the invention claimed in independent claims 1, 15 and 23. Accordingly, Applicants request reconsideration of the §103 rejections of claims 1, 15 and 23 and their respective dependent claims.

CONCLUSION

Applicants have made an earnest and bona fide effort to clarify the issues before the Examiner and to place this case in condition for allowance. Therefore, reconsideration and allowance of Applicants' claims 1-23 are believed to be in order and an early Notice of Allowance to this effect is earnestly solicited.

Respectfully submitted,

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